# IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA GREENSBORO DIVISION

No. 1:18-CV-502-WJO-JLW

LLOYD BUFFKIN JR., et al.  Plaintiffs,	)	
v.	)	PROPOSED CONSENT DECREE
ERIK A. HOOKS, et al.	)	
Defendants.	)	

This Proposed Consent Decree ("Agreement") is entered into by and between Plaintiffs and class representatives Lloyd Buffkin Jr. and Robert Parham ("Class Representatives"), in their capacities as representatives of a class of similarly situated persons (the "Plaintiff Class"), and the North Carolina Department of Public Safety (the "Department"), for itself and for the benefit of Erik Hooks, Abhay Agarwal, Kenneth Lassiter, and Paula Smith (collectively referred to herein as the "Defendants" or "Released Parties").

WHEREAS, the Plaintiff Class, by and through the Class Representatives, who at all relevant times were incarcerated in the custody of the Department, filed the above-captioned case pursuant to 42 U.S.C. § 1983 seeking declaratory and injunctive relief for alleged violations of their Eighth Amendment rights, among other claims; and

WHEREAS, the Class Representatives, Released Parties, and their respective counsel have conferred at length in an effort to reach a mutually-agreeable resolution of the Plaintiff Class's claims for declaratory and injunctive relief;

NOW, THEREFORE, in order to avoid further controversy, expense, inconvenience, and uncertainty, the Class Representatives and Released Parties have agreed upon a full and final settlement of all claims for declaratory and injunctive relief arising out of or connected to the Plaintiff Class's Complaint and Supplemental Complaint, against all Defendants. The parties desire that this settlement be memorialized in this Agreement upon the following terms and conditions:

## 1. HCV Screening and Treatment Goals

The parties share the mutual goals of educating the incarcerated population about hepatitis C virus ("HCV"), reducing the spread of HCV inside correctional facilities, and decreasing the rate of infection within the prisoner population. Therefore, the parties enter into this settlement in an effort to reach those goals.

By this Agreement, the parties intend to expand HCV screening and, at a minimum, maintain current treatment rates with direct-acting antiviral drugs ("DAAs"). To that end, the Department agrees to initiate DAA treatment for at least 2,100 class members between the Effective Date and the conclusion of the Term of this Agreement (as defined below). The parties further agree that nothing in this Agreement shall be construed in a manner that would impede the Department from expanding HCV screening or treatment for prisoners in its custody. For the avoidance of doubt, the parties agree that any shift by the Department to universal opt-out HCV screening shall not constitute a breach of this Agreement or incident of Material Non-Compliance (as defined below).

## 2. Effective Date and Term

This Agreement shall take effect upon final approval by the Court and class members ("Effective Date") and shall remain in effect for five (5) years thereafter, or until counsel for all parties agree otherwise in writing (the "Term"). However, notwithstanding the foregoing, the parties agree that this Agreement shall automatically terminate upon the North Carolina Department of Public Safety ("DPS" or "Department") having treated all class members with DAAs.

## 3. Screening and Education

- a. The Department will increase education around HCV in three distinct ways:
  - i. Within thirty (30) days of the resumption of normal operations, as detailed in the Section hereof entitled "Timing Considerations," or by an earlier date that the Department deems practicable, the Department will place posters that contain general information about HCV and testing and

treatment throughout every DPS facility. The Department will ensure the posters remain displayed throughout the term of this Agreement. These posters shall be substantively consistent with any court-approved class notice regarding this Agreement, shall be printed in English and Spanish, and shall (1) be conspicuously placed in relatively high-traffic areas, (2) describe how HCV is spread, (3) state that prisoners have the ability to receive HCV screening following a request, either through a sick call or during a clinical encounter, (4) state that the virus is more prevalent in correctional settings, and (5) state that the American Association for the Study of Liver Diseases and Infectious Diseases Society of America recommend screening incarcerated persons for the virus. The Department will permit Plaintiffs' counsel at least five (5) business days' advance notice and an opportunity to review the content of the posters and to provide input, which the Department will consider in good faith. However, the Department retains full and final authority over the content of any posters.

- ii. Over the next two years, the Department will begin providing prisoners access to tablets in all facilities. These tablets will contain a variety of educational content, including information (1) describing how HCV is spread, (2) stating prisoners have the ability to receive HCV screening following a request, either through a sick call or during a clinical encounter, (3) stating the risk factors for contracting the virus, (4) stating that the virus is more prevalent in correctional settings, and (5) stating that the American Association for the Study of Liver Diseases recommends screening incarcerated persons for the virus.
- Within sixty (60) days of the resumption of normal operations, as detailed iii. in the Section hereof entitled "Timing Considerations," or by an earlier date that the Department deems practicable, medical personnel will begin including HCV as part of regular infectious disease information sessions conducted at least twice monthly at the Diagnostic Facilities, which are currently Craven Correctional Institution, Piedmont Correctional Institution, Polk Correctional Institution, N.C. Correctional Institute for Women, Foothills Correctional Institution, and Central Prison. At these sessions, medical personnel will provide general information about HCV, including how the virus is transmitted, the risk factors for contracting the virus, its prevalence in correctional settings, the recommendation of the American Association for the Study of Liver Diseases and Infectious Diseases Society of America to screen prisoners for the virus, and an overview of the Department's screening and treatment process. If prisoners who do not understand spoken English attend these sessions, language translators or multilingual staff will be present and will assist these prisoners in understanding the content discussed at these sessions.
- b. Within thirty (30) days of the resumption of normal operations, as detailed in the Section hereof entitled "Timing Considerations," or by an earlier date that the

Department deems practicable, the Department will revise its nursing assessment protocols, including the intake assessment protocol and history and physical forms, to educate prisoners about HCV and offer increased opportunities for screening as follows:

- i. The Department will revise its intake assessment protocol and history and physical form to include standard patient education language about HCV, including the risk factors, prevention, symptoms, testing, and treatment.
- ii. The Department will revise its nursing intake assessment protocol and history and physical form to require staff to ask a patient whether he or she wishes to be screened for HCV, and to document the response.
- iii. The intake assessment protocol will be utilized in two specific patient encounters: (1) upon admission into custody of the Department; and (2) upon each transfer to a new facility for all prisoners; and the history and physical form will be completed by medical providers during a routine physical. Routine physicals are provided to patients 50 years of age or older, at a minimum of once per year. For prisoners who are younger than 50, routine physicals are provided at a minimum of once every five years. Thus, at a minimum, every prisoner will be orally offered opt-in screening at least once every five years.
- c. The Department will continue to ensure screening is available to all prisoners upon request through a sick call and during any clinical encounter.
- d. The Department will explore in good faith strategies for decreasing transmission of HCV among the prison population, including but not limited to expanding:
  - i. access to personal hygiene items; and
  - ii. appropriate access to disinfectant and other cleaning supplies.
- e. Notwithstanding the foregoing, nothing in this Agreement shall be construed to limit the Department's ability to expand screening for HCV, including but not limited to moving to a universal opt-out model of screening.

# 4. Committee Referrals

- **a.** The Hepatitis C Committee ("Committee") will calculate the APRI scores of all prisoners diagnosed with HCV, regardless of projected release date.
- **b.** Prisoners referred to the Committee who have a Projected Release Date ("PRD") that does not allow sufficient time for the Department to evaluate, treat, and arrange for appropriate follow-up before their release from custody will be reported to the Viral Hepatitis Program/HCV Bridge Counseling Program. This program is operated by the

Communicable Disease Branch of the Division of Public Health of the North Carolina Department of Health and Human Services ("NCDHHS"). The Department will provide name and contact information of such patients to a designated Bridge Counselor. The Bridge Counselor shall have access to the patient's lab results. The Department shall also provide the patient with a document showing their latest-calculated APRI score, genotype test result if known, and the dates of each of the foregoing tests.

- **c.** The Committee shall only consider a prisoner's PRD in the decision of whether to recommend evaluation for DAA treatment if, at the time of such evaluation, the prisoner has less time remaining on their sentence than would be required for completing a course of DAA treatment and any necessary follow-up testing.
- **d.** For all prisoners who have sufficient time remaining on their sentences for the Department to evaluate and treat them with DAAs, the Committee will decide whether the referring provider should (i) submit a further referral for treatment evaluation to the Hepatology clinic (or one of the providers that conducts such evaluations), (ii) obtain further labs, or (iii) continue to monitor the patient onsite.
- **e.** Prisoners who are referred to the HCV Bridge Counseling Program, but whose sentences are extended thereafter, shall be referred back to the Committee for consideration at the next Committee meeting after the sentence extension.

# 5. Reporting

- **a.** 180 days after the resumption of normal operations as outlined in the Section hereof entitled hereof entitled "Timing Considerations," the Department shall, at its sole cost and expense, provide Plaintiffs' counsel with one document containing the following information (each such document, a "Status Report"):
  - i. During the previous 180 days ("Reporting Period"), the total number of:
    - 1. new admissions to Department custody;
    - **2.** prisoners in Department custody as of the final day of the Reporting Period;
    - **3.** prisoners offered diagnostic testing for HCV, broken down into those offered testing during:
      - a. admission to Department custody;
      - b. transfer; and
      - c. routine physical examinations as defined in Section 3(b)(iii)
    - **4.** prisoners described in each of subsections 3(i)-(iii), above, who declined diagnostic testing;
    - **5.** prisoners who tested positive for HCV;
    - **6.** prisoners referred to the Committee;
    - 7. prisoners given a priority 1 level designation;

- **8.** prisoners given a priority 2 level designation;
- **9.** prisoners given a priority 3 level designation;
- **10.** prisoners in each priority group whom the Committee referred for DAA treatment;
- 11. prisoners in each priority group who commenced DAA treatment;
- **12.** prisoners referred to the Committee whose projected release date was insufficient to allow for evaluation, treatment, and follow-up before their release;
- 13. prisoners referred to NCDHHS bridge counseling for HCV; and
- **14.** prisoners considered by the Committee who had previously been treated with DAAs but who have either been reinfected with HCV or experienced treatment failure.
- **b.** Beginning with the second Status Report, the Department's Status Reports shall include a list of 10 randomly selected prisoners whom the Committee referred back to their providers for monitoring during the previous Reporting Period and, for each such prisoner, (i) the date on which the Committee referred the prisoner back to the provider, (ii) the date of the HCV monitoring appointment scheduled for the prisoner pursuant to the above-referenced Committee referral, and (iii) an indication of whether that appointment was ultimately kept and, if not, why.
- c. Within one hundred eighty (180) days after resumption of normal operations as outlined in the Section hereof entitled "Timing Considerations," DPS shall, also at its sole cost and expense, provide Plaintiffs' counsel with one document containing the following information (the "Screening Report"): a detailed description of all efforts made within the past 180 days made by DPS to comply with the terms and conditions of Section 3 ("Screening and Education").
- **d.** After the first Status Report, the Department shall, at its sole cost and expense, provide three additional Status Reports, every 180 days, containing updated information relative to items 1 through 16, above.
- **e.** Beginning 180 days after the Department provides the fourth Status Report, Plaintiffs' counsel can request, by certified letter addressed to the General Counsel for the Department, an updated Status Report, to be provided at the Department's sole cost and expense. Plaintiffs' counsel can request up to six additional Status Reports, provided that the Term remains effective.
- **f.** Within 30 days of receipt of a certified letter as described above, the Department, shall, at its sole cost and expense, provide the additional Status Report as requested, containing updated information relative to all items listed in subsections (a) and (b) above.
- **g.** Plaintiffs' counsel shall maintain the confidentiality of all Status Reports and the Screening Report consistent with the terms and conditions of the May 30, 2019 Consent Protective Order entered in the above-referenced case (the "Protective Order"). *See*

- Dkt. 63. In addition to the obligations set forth in the Protective Order, Plaintiffs' counsel specifically agree to keep confidential and not disclose to any third party any Protected Health Information (PHI) or Individually Identifiable Health Information (IIHI), as those phrases are defined in 45 CFR 160.103, or Personally Identifiable Information (PII), as that phrase is defined in 2 CFR 200.79.
- h. Plaintiffs' counsel further agrees that in the event of a breach or inadvertent disclosure of data held by Plaintiffs' counsel, or any other event which results in any amount of PHI, IIHI, or PII held by Plaintiffs' counsel being accessed by any person or entity not authorized to view such information under the Protective Order or subsection (e) above, Plaintiffs' counsel agree to fully defend, indemnify and hold harmless the Department and any of its agents, from any and all claims, demands, causes of action of loss, harm, or damage, whatsoever, in any way arising from such event.

## 6. Modification of CP-7

The Department shall modify the clinical practice guideline, CP-7, as reflected in Exhibit B to this Agreement. The modified guideline shall take effect within thirty (30) days of the Effective Date of this Agreement. The following definitions apply to Step 4(b) in Exhibit B:

- "Complications" means a variety of circumstances such as being on certain immunosuppressant medications, or having a number of other medical conditions.
- "Focused physical examination" means a physician's assessment and examination of the patient to collect objective data and physical findings as it relates to a patient's specific medical condition.
- "Focused review of systems" means a physician's assessment and examination of the patient to collect subjective data and physical findings as it relates to a patient's specific medical condition.
- "Patient education relevant to HCV" means educational counseling by a medical provider regarding prevention and transmission, risk factors, testing, and medical management of HCV infection.
- "Significant comorbidities" include but are not limited to cryoglobulinemia with renal disease or vasculitis, certain types of lymphomas or hematologic malignancies, porphyria cutanea tarda, HBV, HIV, comorbid liver diseases (e.g., autoimmune hepatitis, hemochromatosis, fatty infiltration of the liver, steatohepatitis), diabetes mellitus, and kidney disease.

## 7. Timing Considerations.

In light of the COVID-19 pandemic and the consequent state and national states of emergency, the Division of Prisons (the agency within the Department responsible for operating state prison facilities) has been placed on an emergency footing and transitioned to an Incident Command management structure. Given these exigent circumstances and the consequent unique health, administrative, and custodial challenges, essential correctional and medical staff must focus almost exclusively on the administration and management of direct and immediate correctional issues. As a result, the Department's ability to comply with certain terms provided in this

agreement will be delayed. Therefore, Plaintiffs agree and understand that the timelines provided for in Sections 3 and 5 will begin the day after the Division of Prisons resumes its normal operations. Normal operations means when the Division of Prisons is no longer operating on an Incident Command management structure.

# 8. No Admission of Liability

Nothing in this Agreement shall be construed in any way as an admission by the Department of any liability or wrongdoing whatsoever. The Department specifically disclaims any liability or wrongdoing whatsoever on the part of itself, its agents, and employees. This Agreement may not be relied upon as precedent in any future claim and shall not in any way be construed as an admission, presumption, or concession by any Defendant of any liability or wrongdoing whatsoever.

#### 9. Release of Claims

For purposes of this Section, the following definitions shall apply:

"Releasees" means the Defendants, their directors, officers, agents, contractors, attorneys, and employees, past and present, as well as the successors of the same.

"Releasors" means the Plaintiffs, the Plaintiff class and their respective heirs, executors, administrators, and successors.

In exchange for the programmatic, protocol, and policy changes, as well as the other covenants undertaken by Defendants in this Agreement, Releasors do hereby release, acquit, and discharge Releasees of and from any and all charges, claims, demands, and causes of action seeking injunctive or declaratory relief, of whatever kind or nature, whether known or unknown, either (a) arising from or in any way related to the diagnosis or treatment of Hepatitis C as provided in CP-7, effective September 2015, and interim CP-7, effective March 2019, including those alleged or set forth in this action, or (b) arising out of or in any way connected with any transactions, occurrences, acts or omissions set forth or facts alleged in the aforesaid action, which the Releasors ever had, now have or hereafter can, shall or may, have for, upon, or by reason of any matter, cause or thing whatsoever which occurred prior to the execution of this Agreement. The foregoing shall not waive any ability class members may have to seek damages, compassionate release or extended limits of confinement. Notwithstanding the foregoing, the parties reserve the right to move the Court for any reasonable attorneys' fees and costs they would otherwise be legally entitled to seek to recover stemming from litigation of the class claims following Court approval of this Agreement.

## 10. Final Approval.

All Parties agree that this Agreement represents a full and fair resolution of the Class Claims. This Agreement shall be subject to the final approval of the Court. The Parties shall cooperate in presenting this Agreement to the Court for final approval and/or at any hearing under Rule 23(e) of the Federal Rules of Civil Procedure. If the Court does not grant final approval, this

Agreement shall be null and void and of no force and effect, and nothing herein shall be deemed to prejudice the position of any party with respect to this action or otherwise, and neither the existence of this Agreement, nor any of its terms or provisions, nor any of the negotiations or proceedings connected with it, shall be admissible in evidence, referred to for any purpose in this action or in any other litigation or proceeding, or construed as an admission, presumption, or concession by any party of any liability or the truth of any of the allegations in this action. This Agreement may be enforced only by the parties hereto or their successors in interest.

#### 11. Dismissal

- a. The parties consent and stipulate to the U.S. District Court for the Middle District of North Carolina's continuing jurisdiction to enforce this Agreement through its Term.
- b. Within thirty (30) days of the later of (a) the resumption of normal operations, as detailed in the Section hereof entitled "Timing Considerations," and (b) final District Court approval of this Agreement, the parties shall jointly move the District Court to enter an Order administratively closing this action and stating that the District Court retains jurisdiction to enforce this Agreement for the duration of its term. At the conclusion of the Term or upon final resolution of any outstanding motion to compel compliance, whichever is later, the parties will jointly move to dismiss this action with prejudice.
- c. The parties agree to cooperate, execute any and all reasonable and necessary supplementary documents, and take all additional reasonable actions that may be necessary to give full force and effect to the terms of this Agreement.

## 12. Dispute Resolution

- a. Within thirty (30) days of Plaintiffs' counsel learning that the Department has failed to materially comply with the terms of this Agreement ("Material Non-Compliance"), counsel for the parties shall meet and confer in good faith regarding the Material Non-Compliance and measures to be taken by the Department to remedy it. For the first three Reporting Periods, any regression of more than 10% from one Reporting Period to the next in the number of patients who began DAA treatment during the Reporting Period shall be considered an instance of Material Non-Compliance. For the remaining Reporting Periods, any regression of more than 10% from the average number of patients who began DAA treatment in the first three Reporting Periods shall be considered an instance of Material Non-Compliance. Notwithstanding the foregoing, the parties agree that any minor or incidental breach or delay in implementation of a provision of this Agreement shall not constitute Material Non-Compliance.
- b. Within sixty (60) days of a meeting under subsection (a), the Department shall submit one document to Plaintiffs' counsel detailing the progress the Department has made in implementing the aforementioned measures.

c. Within thirty (30) days of Plaintiffs' counsel's receipt of the Status Report for the subsequent Reporting Period, counsel for the parties shall meet and confer in good faith, unless counsel jointly agree otherwise. Only if the Department has not remedied the instance of Material Non-Compliance identified during the prior Reporting Period, Plaintiffs may move the U.S. District Court for the Middle District of North Carolina to compel the Department's compliance with the terms of this Agreement. Further, only if the Court grants Plaintiffs relief following their motion to compel compliance and Defendants' next Status Report reflects that the Department has failed to remedy the Material Non-Compliance that formed the basis of Plaintiffs' motion, Plaintiffs may re-open this litigation on the merits in the Middle District of North Carolina if necessary for the limited purpose of resolving the non-compliance at issue.

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[SIGNATURE PAGES TO FOLLOW]

IN WITNESS WHEREOF and intending to be legally bound hereby, the parties have executed this Proposed Consent Decree on the date written next to their respective signatures. This the 3 day of 5ep1. 2020. Class Representative This the 3rd day of Sept. , 2020. Enity E. Su Emily E. Seawell ACLU of North Carolina Legal Foundation PO Box 28004 Raleigh, NC 27611 Class Counsel This the 3rd day of Sept. , 2020. Daniel K. Siegel ACLU of North Carolina Legal Foundation PO Box 28004 Raleigh, NC 27611 Class Counsel This the  $3^{\circ}$  day of 5ept., 2020. Michele Luecking-Sunman N.C. Prisoner Legal Services, Inc. PO Box 25397 Raleigh, NC 27611

Class Counsel

IN WITNESS WHEREOF and intending to be legally bound hereby, the parties have executed this Proposed Consent Decree on the date written next to their respective signatures. This the 3 day of 5 pp+, 2020. Robert B. Parham Class Representative This the 3rd day of Sept. , 2020. Enity E. Su Emily E. Seawell ACLU of North Carolina Legal Foundation PO Box 28004 Raleigh, NC 27611 Class Counsel This the 3rd day of Sept. , 2020. Daniel K. Siegel ACLU of North Carolina Legal Foundation PO Box 28004 Raleigh, NC 27611 Class Counsel This the  $3^{\text{rd}}$  day of  $5e\rho$ ., 2020.

> Michele Luecking-Sunman N.C. Prisoner Legal Services, Inc. PO Box 25397 Raleigh, NC 27611 Class Counsel

IN WITNESS WHEREOF and intending to be legally bound hereby, the parties have executed this Proposed Consent Decree on the date written next to their respective signatures.

This the 9 day of Sept., 2020.

Timothy Moose

Chief Deputy Secretary

N.C. Department of Public Safety

This the Oday of Septem 2020.

JOSHUA H. STEIN Attorney General

Orlando L. Rodriguez

Assistant Attorney General

N.C. Department of Justice

Public Safety Section

Post Office Box 629

Raleigh, North Carolina 27602-0629

Attorney for Defendants

# Exhibit B Step 4b

#### Step 4b

- Providers must periodically monitor all Patients with active HCV infection, including acute cases, treatment failures, relapse of infection or reinfection, and those with chronic HCV infection who have not yet been treated with DAAs.
- All patients that are referred back to their providers will be evaluated as follows:
  - The provider will conduct a clinical encounter to conduct a focused review of systems and patient education relevant to HCV;
  - The provider will assess vital signs and conduct a focused physical examination; and
  - The provider will also monitor relevant labs, including but not limited to CBC, liver panel, serum creatinine, calculated GFR, and calculation of the APRI score.
- The above-described evaluation will occur at least every six months, and more frequently as clinically indicated.
- Following the conclusion of the evaluation described above, the provider will again refer Patients with chronic HCV to the Hepatitis C Committee if there has been any change in their condition, including but not limited worsening in renal function or the APRI score.
- The providers at the facility will continue to monitor patient until enters treatment
- Treatment for cases of acute HCV infection will be deferred to allow for spontaneous clearance of viremia, unless there is a compelling reason to treat the acute infection in order to prevent severe complications, e.g., HCV infection superimposed on established cirrhosis or advanced fibrosis
  - Patients with acute HCV infection should be monitored to determine the outcome of infection (spontaneous viral clearance versus chronic infection). This is done by retesting HCV RNA over a period of time. The provider will check HCV RNA at 12 weeks following exposure (or following diagnosis if the infection date is unknown). Spontaneous clearance is likely in those who have a negative HCV RNA at this time point.
  - Patients who appear to have cleared HCV RNA should have subsequent HCV RNA determinations to ensure that clearance was sustained (ie, at least two negative HCV RNA tests at least 12 weeks apart and at least 6 months beyond the estimated date of exposure.
  - Those who have a positive HCV RNA after six months are considered to have chronic HCV infection, and the provider should manage the case as a chronic infection at this point.